DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 20, 2015

CrossBay Medical, Inc.
% Cindy Domecus
Regulatory Consultant
Domecus Consulting Services, LLC
1171 Barroilhet Avenue
Hillsborough, CA 94010

Re: K142545
Trade/Device Name: CrossBay SonoFlow Sonohysterography and Sonohysterosalpingography Device
Regulation Number: unclassified
Regulation Name: unclassified
Regulatory Class: unclassified
Product Code: LKF
Dated: February 14, 2015
Received: February 18, 2015

Dear Cindy Domecus,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142545

Device Name
CrossBay SonoFlow Sonohysterography and Sonohysterosalpingography Device

Indications for Use *(Describe)*
The CrossBay SonoFlow Sonohysterography and Sonohysterosalpingography Device is indicated for use to access the uterine cavity for sonohysterography and sonohysterosalpingography procedures. The SonoFlow Device can instill saline-only or a mixture of saline and air for performance of saline infusion sonohysterography and sono-hysterosalpingography (Sono-HSG), respectively, for the evaluation of the fallopian tubes and/or the uterus. The following are generally recognized clinical indications for saline infusion sonohysterography and sonohysterosalpingography procedures: suspected polyps, fibroids, adhesions, endometrial thickening, and/or the selective evaluation of fallopian tube patency.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (21 CFR § 807.92(c))
K142545

I. SUBMITTER INFORMATION

Submitter: CrossBay Medical, Inc.
793 Sandoval Way
Hayward, CA 94544

Contact: Cindy Domecus
Regulatory Consultant to CrossBay Medical
Phone: 650.343.4813
Fax: 650.343.7822
Email: domecusconsulting@comcast.net

Date Summary Prepared: 14 February 2015

II. SUBJECT DEVICE INFORMATION

Device Trade Name: CrossBay Medical SonoFlow™ Sonohysterography and SonoHysterosalpingography Device
Common Name: Hysterosonography and Hysterosalpingography Catheter
Regulatory Class: Unclassified
Submission Type: 510(k)
Product Code: LKF (Cannula, Manipulator/Injector, Uterine)

III. PREDICATE & REFERENCE DEVICE INFORMATION

- **Primary Predicate Device -** Femasys, Inc. - FemVue Saline-Air Device (K110288 – April 28, 2011)
- **Predicate Device -** Femasys Inc. - FemVue Catheter System (K083690 – June 23, 2009)
- **Reference Device -** CrossBay Medical Inc. - SonoSure Sonohysterography and Endometrial Sampling Device (K133144 – March 19, 2014)

IV. DEVICE DESCRIPTION

The CrossBay Medical SonoFlow™ Device is a catheter that enables saline and air infusion of contrast media to perform sonohysterosalpingography and sonohysterography procedures. The catheter is comprised of standard polymer materials and contains a silicone acorn tip to enable a cervical seal. The distal end of the device contains an aeration component that provides an alternating pattern of saline and air as a stream of contrast media into the uterus and fallopian tubes. The proximal end of the device

contains a handle with an air supply opening that allows the physician to reduce or eliminate the amount of air infusion selectively by occluding the opening of the air supply. The proximal end of the device contains an empty PVC bag that can be filled with saline. The device is provided sterile and is intended for single use only.

V. INDICATIONS FOR USE

The CrossBay SonoFlow Sonohysterography and Sonohysterosalpingography Device is indicated for use to access the uterine cavity for sonohysterography and sonohysterosalpingography procedures. The SonoFlow Device can instill saline-only or a mixture of saline and air for performance of saline infusion sonohysterography and sono-hysterosalpingography (Sono-HSG), respectively, for the evaluation of the fallopian tubes and/or the uterus. The following are generally recognized clinical indications for saline infusion sonohysterography and sonohysterosalpingography procedures: suspected polyps, fibroids, adhesions, endometrial thickening, and/or the selective evaluation of fallopian tube patency.

The Indications for Use Statement is not identical to each predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the subject and predicate devices have the same intended use – for use during sonohysterography and sonohysterosalpingography procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The subject and predicate devices are catheter based technologies that employ the use of similar materials of construction and share similar principles of operation. The devices are used during hysterosalpingography and hysterosonography procedures. At a high level, the subject and predicate devices share the following technological characteristics:

- Devices are all catheter based or require use of a catheter based device.
- Devices have similar dimensions and are comprised of standard medical grade materials.

The following technological differences exist between the subject and primary predicate device (FemVue Saline-Air):

- The primary predicate device requires the use of a separate uterine catheter and saline / air infusion device; the subject device combines these functions.
- The primary predicate device requires simultaneous air and saline infusion; the subject device contains a device feature that enables selective infusion of air within the saline media.

The different technological characteristics of the subject device do not raise different types of safety and effectiveness questions as they are routinely encountered during premarket review of saline infusion sonohysterography and Sono-HSG devices.

Accepted scientific methods exist to assess the effects of the different technological characteristics, including mechanical, animal, and/or clinical performance testing. The submission included sufficient

performance data to assess the effects of the different technological characteristics, and the performance data demonstrate equivalence.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Bench Testing

Bench testing confirmed that the CrossBay Medical SonoFlow Device performs according to the product specifications. Device evaluation consisted of functional testing performed pursuant to the device verification protocol. Bench testing included verification of device functionality, bond and joint tests of components, and an evaluation of the device's ability to deliver fluid and air. These tests were conducted on ethylene oxide sterilized units at baseline and on devices subjected to accelerated aging conditions equivalent to six (6) months and passing results were obtained.

Biocompatibility testing

The subject CrossBay SonoFlow device contains the same materials as the reference Cross Bay SonoSure device. Additionally, the subject device is manufactured by the same contract manufacturer using similar processes to that employed for the predicate device. As such, the biocompatibility data previously provided in K133144 for the CrossBay SonoSure device is applicable to the subject device. The biocompatibility evaluation for the CrossBay SonoSure device was conducted in accordance with the requirements defined in ISO 10993 "Biological Evaluation of Medical Devices" and FDA's guidance ("Use of International Standard ISO 10993", draft document issued on 24 April 2013 and BlueBook Memorandum #G95-1 dated 01 May 1995). Testing included the following: 1) Cytotoxicity; 2) Vaginal Irritation; and, 3) Sensitization and demonstrated biocompatibility.

Sterilization Validation

The subject CrossBay SonoFlow device has equivalent components, materials, dimensions and weight as the reference Cross Bay SonoSure device. Additionally, the subject device is sterilized by the same contract sterilizer as the reference device using the same methodology. As such, the sterilization data previously provided in K133144 for the CrossBay SonoSure device is applicable to the subject device. The sterilization validation for the CrossBay SonoSure device complies with the requirements prescribed in the applicable standards for ethylene oxide sterilization (ISO 11135-1:2007 "Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices" and ISO 10993-7:2008 "Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals").

Packaging and Shipping Validation

Packaging and shipping validation studies were successfully conducted on sterilized CrossBay Medical SonoFlow Devices pursuant to the applicable ASTM guidelines: ASTM F1929 "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration"; D642 "Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components and Unit Loads"; and, 5276 "Standard Test Method for Drop Test of Loaded Containers by Free Fall". Passing results were obtained.

VIII: CONCLUSIONS

The CrossBay Medical SonoFlow Device is substantially equivalent to the proposed predicate devices.